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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,887	04/06/2005	Vladimir Velebny	074047.2	6569

27805 7590 07/07/2009

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
07/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,887	VELEBNY ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-30 and 32-38* is/are pending in the application.

4a) Of the above claim(s) *6-26 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,27-30 and 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendment filed April 15, 2009 has been received and entered into present application. No claims were canceled and claim 38 was added by applicant. Claims 6-26 remain withdrawn and claim 38 is also withdrawn, as detailed below and thus claims 1-4, 27-30, and 32-37 are pending.

Claim 38, newly added, is drawn to a product by process and had it been included in the original disclosure would have been considered a process as its special technical feature is the mixing of sodium hyaluronate and iodine/potassium iodide at neutral pH which is distinct from the special technical feature of the composition which does not require either sodium hyaluronate or a neutral pH upon mixing. Thus claim 38 is withdrawn, under election by original presentation.

Applicants' arguments, filed April 15, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103 (new grounds of rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 27-30, and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drizen et al. (US 2002/0037319 A1) in view of Cantor et al. (US 20030054025 A1), Cantor et al. is already of record in the office action dated October 16, 2008.

In claim 1, applicant claims a composition for wound healing comprising a salt of hyaluronic acid with a molecular weight between 200,000 to 2,500,000, and iodine and potassium iodide in the form of a sterile aqueous solution at neutral pH. Drizen et al. teach that hyaluronic acid and its salts are useful for wound healing (page 3, [0043]) and teaches that has a negative charge at neutral pH and is soluble in water where it forms very viscous solutions (page 3, [0045]) and they teach specifically using hyaluronic sodium with molecular weights between 650,000-800,000 (page 4, [0049]) and in example 1 teach 2.5% of hyaluronate in their composition (page 11, [0205]) which is an aqueous wound healing composition. They do not teach iodine and

potassium iodide, however those are both known in the art for use in wound healing. Cantor et al. teaches antimicrobial agents such as iodine complexes with potassium iodide (page 5, [0048]) as preferred agents. It would have been obvious to one of ordinary skill in the art at the time of the invention to add known antimicrobial agents such as the iodine-potassium iodide complex taught by Cantor et al. to the wound healing compositions of Drizen et al. Drizen et al. does not explicitly state that their compositions are neutral but given that hyaluronic acid can be put into solution at a neutral pH it would be obvious, and preferable to have a composition that is applied to a human to be at a neutral pH. Optimizations such as how much water is in the composition of Drizen et al. would be easily done to fit the particular situation or product formulation (solution to be dropped on a wound, gel to be applied to a wound, dried composition onto a bandage formulation, etc). There is obvious motivation to form the product how it is desired by the consumer and would be easily done. Thus claim 1 is unpatentable over Drizen et al. in view of Cantor et al.

In claim 2, applicant claims that the salt includes sodium salt. As mentioned above Drizen et al. teaches sodium hyaluronate (page 11, [0205]) and thus claim 2 is also unpatentable over Drizen et al. in view of Cantor et al.

In claim 27, applicant claims a composition to enhance wound healing comprising iodine, potassium iodide, and hyaluronic acid in a composition that is formulated at a solution at neutral pH. As discussed above, it would be obvious to one of ordinary skill in the art at the time of the invention to combine the iodine/potassium iodide solution of Cantor et al. with the wound healing composition comprising

hyaluronic acid of Drizen et al. Thus claim 27 is also unpatentable over Drizen et al. in view of Cantor et al. for the reasons discussed above.

In claims 3-4, 28, and 34, applicant claims that the concentration of hyaluronic acid is 0.05-10%, the concentrations of iodine and potassium iodide are from 0.05-2.5% (claim 3) or 0.075-1% (claim 4) each or 0.05-2.5% of iodine and 0.05-5% of potassium iodide (claim 28). As discussed above Drizen et al. teaches 2.5% of sodium hyaluronate. Cantor et al. teaches the combination of iodine and potassium iodide but does not teach percentages. As discussed in the previous office action, it would be obvious to one of ordinary skill in the art that both iodine and potassium iodide are well known in the art, and the concentration of those can be easily optimized and the concentration of hyaluronic acid would be a good starting point for such a concentration. Applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Thus claims 3-4, 28, and 34 are unpatentable over Drizen et al. in view of Cantor et al.

In claim 29, applicant claims the composition of claim 27 where the iodine is added to the potassium iodide solution for combining with a hyaluronate solution. As discussed above, Cantor et al. teaches an iodine/potassium iodide solution and as

discussed above it would be obvious to combine that with the hyaluronic acid of Drizen et al. Thus claim 29 is unpatentable over Drizen et al. in view of Cantor et al.

In claim 30, applicant claims the composition of claim 27, wherein the hyaluronic acid has a molecular weight of 200,000 to 2,500,000. As discussed above, Drizen et al. teaches 650,000-800,000 (page 4, [0049]) and thus claim 30 is also unpatentable over Drizen et al. in view of Cantor et al.

In claim 32, applicant claims that the salt includes sodium salt. As mentioned above Drizen et al. teaches sodium hyaluronate (page 11, [0205]) and thus claim 32 is also unpatentable over Drizen et al. in view of Cantor et al.

In claim 33, applicant claims that the hyaluronic acid is used between 0.05-10% by weight. Drizen et al. teaches 2.5% (page 11, [0205]) and thus claim 33 is also unpatentable over Drizen et al. in view of Cantor et al.

In claims 35-36, applicant claims the composition of claim 27 is prepared by combining iodine with hyaluronic acid (claim 35) or the iodine is dissolved in an aqueous solution of potassium iodide to form the iodine solution (claim 36). Cantor to et al. teaches a composition with both iodine and potassium iodide and thus it would be obvious to mix the two together and then mix with hyaluronic acid. Furthermore the claims are drawn to a composition, not a process and therefore the steps are not required to be taught by the prior art as long as the end product is the same. Thus claims 35-36 are unpatentable over Drizen et al. in view of Cantor et al.

In claim 37, applicant claims the composition of claim 27 is viscous. Drizen et al. teaches that hyaluronic acid forms viscous solutions at neutral pH in water (page 3,

[0045]), and thus it would be obvious that the solution of Drizen et al. would be viscous. Furthermore, this is well within the skill of one of ordinary skill in the art to make the solution viscous for better application to the wound. Thus claim 37 is also unpatentable over Drizen et al. in view of Cantor et al.

This new rejection was necessitated by the amendments to the claims.

Conclusion

Rejection of claims 1-4, 27-30, and 32-37 is deemed proper and is **maintained.**

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614